

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. 97P-0354]

OMB

Display Date	2-27-01
Publication Date	2-28-01
Certifier	SN Reese

Medical Devices; Reclassification of the Shoulder Joint Metal/Polymer/Metal Nonconstrained or Semi-Constrained Porous-Coated Uncemented Prosthesis

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is reclassifying the shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis intended to replace a shoulder joint from class III to class II (special controls). The agency is also announcing that it has issued an order in the form of a letter to the Orthopedic Surgical Manufacturers Association (OSMA) reclassifying the device. The special control that will apply is a guidance document entitled "Class II Special Controls Guidance: Shoulder Joint Metal/Polymer/Metal Nonconstrained or Semi-Constrained Porous-Coated Uncemented Prosthesis." The agency is classifying this device into class II because special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish special controls.

DATES: This rule is effective *[insert date 30 days after date of publication in the Federal Register]*.

FOR FURTHER INFORMATION CONTACT: Theodore R. Stevens, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2036.

SUPPLEMENTARY INFORMATION:

I. Background (Regulatory Authorities)

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et. seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94-295), the Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101-629), and the Food and Drug Administration Modernization Act of 1997 (the FDAMA) (Public Law 105-115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: (1) The device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with new section 513(f)(2) of the act, as amended by the FDAMA; or (3) FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Reclassification of postamendments devices is governed by section 513(f)(3) of the act, formerly section 513(f)(2) of the act. This section provides that FDA may initiate the reclassification of a device classified into class III under section 513(f)(1) of the act, or the manufacturer or importer of a device may petition the Secretary of Health and Human Services (the Secretary) for the issuance of an order classifying the device in class I or class II. FDA's regulations in § 860.134 (21 CFR 860.134) set forth the procedures for the filing and review of a petition for reclassification of such class III devices. In order to change the classification of the device, it is necessary that the proposed new class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

The FDAMA added a new section 513(f)(2) to the act which addresses classification of postamendments devices. New section 513(f)(2) of the act provides that, upon receipt of a "not substantially equivalent" determination, a 510(k) applicant may request FDA to classify a postamendments device into class I or class II. Within 60 days from the date of such a written request, FDA must classify the device by written order. If FDA classifies the device into class I or II, the applicant has then received clearance to market the device, and it can be used as a predicate device for other 510(k)'s. It is expected that this process will be used for low risk devices. This process does not apply to devices that have been classified by regulation into class III, i.e., preamendments class III devices, or class III devices for which a PMA is appropriate.

Under section 513(f)(3)(B)(i) of the act, formerly section 513(f)(2)(B)(i) of the act, the Secretary may, for good cause shown, refer a petition to a device classification panel. If a petition is referred to a panel, the panel shall make a recommendation to the Secretary respecting approval or denial of the petition. Any such recommendation shall contain: (1) A summary of the reasons

for the recommendation, (2) a summary of the data upon which the recommendation is based, and (3) an identification of the risks to health (if any) presented by the device with respect to which the petition was filed.

II. Recommendation of the Panel

On July 23, 1997, FDA filed the reclassification petition submitted by OSMA, requesting reclassification of the shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis intended to replace a shoulder joint from class III to class II. FDA consulted with the Orthopedic and Rehabilitation Devices Panel (the Panel) regarding the reclassification petition. During an open public meeting on January 12 and 13, 1998, the Panel recommended that FDA reclassify the shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis intended to replace a shoulder joint from class III to class II. The Panel recommended that the special controls for the device be FDA guidance documents, consensus standards, and postmarket surveillance.

FDA considered the Panel's recommendation and tentatively agreed that the generic type of device, the shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis intended to replace a shoulder joint, be reclassified from class III to class II. FDA agrees that guidance documents and consensus standards are appropriate special controls for the device.

FDA disagrees with the Panel that postmarket surveillance is a necessary or an appropriate special control for the device. In their deliberations, the Panel stated that it was important that adverse device outcomes should be reported to FDA and should be tracked through postmarket surveillance. FDA believes that another postmarket mechanism better addresses the Panel's concern. FDA believes that the existing mandatory Medical Device Reporting system is the appropriate mechanism to report such adverse events. Therefore, postmarket surveillance is unnecessary to address the Panel's concerns and to reasonably assure the safety and effectiveness of the device.

Subsequently, in the **Federal Register** of May 28, 1999 (64 FR 29043), FDA issued the Panel's recommendation for public comment. FDA received two comments on the Panel's recommendation. Both comments supported the Panel's recommendation to reclassify the device into class II. One comment also provided updated information on the designations (years of issuance) and the titles for six of the American Society for Testing and Materials (ASTM) consensus standard special controls for the device. FDA agrees with these comments and will incorporate the updated designations and titles in the special control for the device.

After reviewing the data in the petition and presented before the Panel, and after considering the Panel's recommendation and the comments on the notice of panel recommendation, FDA issued an order to the petitioner on December 17, 1999, reclassifying the shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis intended to replace a shoulder joint, and substantially equivalent devices of this generic type, from class III to class II with the implementation of special controls.

The special controls listed in the order to the petitioner were FDA guidance documents and consensus standards. The FDA guidance documents were as follows:

1. "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement;"
2. "Guidance Document for Testing Non-articulating, 'Mechanically Locked' Modular Implant Components;"
3. "Draft Guidance Document for the Preparation of Premarket Notification (510(k)) Applications for Orthopedic Devices-The Basic Elements;"
4. "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing;" and
5. "510(k) Sterility Review Guidance (# K90-1)," 2/12/90.

The ASTM consensus standards were as follows:

1. F 67-95, "Standard Specifications for Unalloyed Titanium for Surgical Implant Applications;"

2. F 75-98, "Standard Specification for Cobalt-28 Chromium-6 Molybdenum Casting Alloy and Cast Products for Surgical Implants (UNS R30075);"
3. F 136-98, "Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial Alloy (UNS R56401)) for Surgical Implant Applications;"
4. F 648-98, "Standard Specification for Ultra-High Molecular Weight Polyethylene Powder and Fabricated Form for Surgical Implants;"
5. F 1044-95, "Standard Test Method for Shear Testing of Porous Metal Coatings;"
6. F 1147-99, "Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings;"
7. F 1160-98, "Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical Coatings;"
8. F 1377-98a, "Standard Specification for Cobalt-28 Chromium-6 Molybdenum Powder for Coating of Orthopedic Implants (UNS R30075);"
9. F 1378-99, "Standard Specification for Shoulder Prostheses;" and
10. F 1580-95, "Standard Specification for Titanium and Titanium-6% Aluminum-4% Vanadium Alloy Powders for Coatings of Surgical Implants."

FDA has recently incorporated the 5 FDA guidance documents and the 10 ASTM consensus standards into a special control guidance entitled "Class II Special Controls Guidance: Shoulder Joint Metal/Polymer/Metal Nonconstrained or Semi-Constrained Porous-Coated Uncemented Prosthesis." This guidance document is now the special control for this generic device.

Accordingly, as required by § 860.134(b)(6) and (b)(7) of the regulations, FDA is announcing the reclassification of the generic shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis intended to replace a shoulder joint from class III into class II. On December 17, 1999, FDA issued an order to OSMA reclassifying the shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis into class II. In addition, FDA is issuing this final rule to codify the reclassification of the device by adding new § 888.3670.

III. Access to Special Controls

Persons interested in obtaining a copy of an FDA guidance may do so using the Internet. The Center for Devices and Radiological Health (CDRH) maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. Guidance documents are also available from the Division of Small Manufacturers Assistance (DSMA) (HFZ-220), Food and Drug Administration, Center for Devices and Radiological Health, 1350 Piccard Dr., Rockville, MD 20850. In order to receive the FDA guidance documents via your fax machine call the CDRH Facts-On-Demand (FOD) system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system and enter the document number followed by the pound sign (#). Follow the remaining voice prompts to complete your request. The document number is 1193 for "Class II Special Controls Guidance: Shoulder Joint Metal/Polymer/Metal Nonconstrained or Semi-Constrained Porous-Coated Uncemented Prosthesis."

IV. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-612 (as amended by subtitle D of the Small Business Regulatory Fairness Enforcement Act of 1996 (Public Law 104-121))), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental,

public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of the device from class III to class II will relieve all manufacturers of the device of the cost of complying with the premarket approval requirements in section 515 of the act. Because reclassification will reduce regulatory costs with respect to this device, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that this final rule will not have a significant economic impact on a substantial number of small entities. In addition, this final rule will not impose costs of \$100 million or more on either the private sector or State, local, or tribal governments in the aggregate, and therefore a summary statement or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

VII. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 888

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 888 is amended as follows:

PART 888—ORTHOPEDIC DEVICES

1. The authority citation for 21 CFR part 888 continues to read as follows:

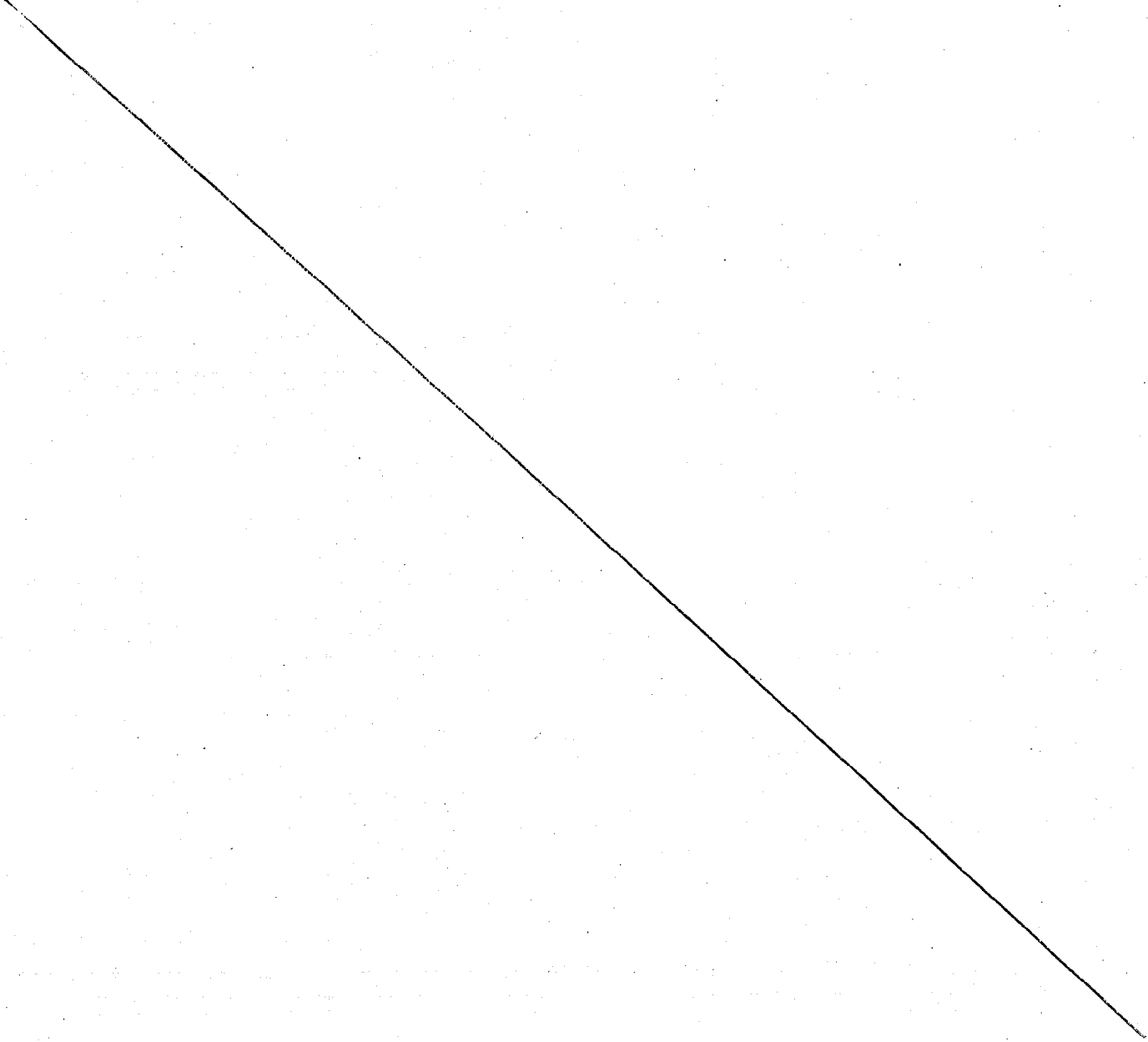
Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 888.3670 is added to subpart D to read as follows:

§ 888.3670 Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis.

(a) *Identification.* A shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis is a device intended to be implanted to replace a shoulder joint. The device limits movement in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a humeral component made of alloys such as cobalt-chromium-molybdenum (Co-Cr-Mo) and titanium-aluminum-vanadium (Ti-6Al-4V) alloys, and a glenoid resurfacing component made of ultra-high molecular weight polyethylene, or a combination of an articulating ultra-high molecular weight bearing surface fixed in a metal shell made of alloys such as Co-Cr-Mo and Ti-6Al-4V. The humeral component and glenoid backing have a porous coating made of, in the case of Co-Cr-Mo components, beads of the same alloy or commercially pure titanium powder, and in the case of Ti-6Al-4V components, beads or fibers of commercially pure titanium or Ti-6Al-4V alloy, or commercially pure titanium powder.

The porous coating has a volume porosity between 30 and 70 percent, an average pore size between 100 and 1,000 microns, interconnecting porosity, and a porous coating thickness between 500 and 1,500 microns. This generic type of device is designed to achieve biological fixation to bone without the use of bone cement.



(b) *Classification*. Class II (special controls). The special control for this device is FDA's "Class II Special Controls Guidance: Shoulder Joint Metal/Polymer/Metal Nonconstrained or Semi-Constrained Porous-Coated Uncemented Prosthesis."

Dated: 2-4-01
February 4, 2001.

Linda S. Kahan

Linda S. Kahan,
Deputy Director for Regulations Policy,
Center for Devices and Radiological Health.

[FR Doc. 01-???? Filed ??-??-01; 8:45 am]

BILLING CODE 4160-01-F

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

Suzette N. Rose